

History

of the

U. S. Food and Drug Administration

Interviewee: Sterk Larson

Interviewer: Robert G. Porter
Ronald T. Ottens

Date: June 2, 1992

Place: Bowie, Md.

DEED OF GIFT

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RO: This is another in a series of interviews on the history of the Food and Drug Administration. Today we're interviewing Sterk Larson, a retired FDA employee, in his home in Bowie, Maryland. The date is June 2, 1992. Interviewing Mr. Larson is Robert G. Porter and Ronald T. Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's Oral History Program.

Sterk, to start this interview, would you briefly sketch your education, where and when you were born, and the background of how you came to FDA?

SL: I was born in 1932 in Madison, Wisconsin. Let's see. My education was at the University of Wisconsin after three years in the military, where I was in Germany in the army. I got a B.S. in the original science, economics, with a minor in geography. Then I did some graduate studies at American University and George Washington University. When I was in the army I always questioned our government system and how things were managed, and I said, "By gosh, when I get out of college, I'm going to go in there and straighten that place up." So that's part of the reason why I wanted to work for the federal government. An opportunity came to work for about three places, and FDA sounded the most interesting and most in need of a . . .

RO: Of your expertise.

SL: Yes. And that's (Inaudible). Anyway, I started out in Chicago in 1959 as a management assistant under the tutelage of R. G. Porter on occasion. (Laughter)

RO: Who was the director in Chicago at that time?

SL: What are you asking me all this stuff for?

RP: Was it (John) Guill? Or was it before that?

SL: I think it was Guill. I think Guill just came in there. He was brand new. I was trying to think of the chief inspector. He had a mustache. I always called him mustache.

RP: Bill Kupp?

SL: Yes.

RP: Bill Kupp.

RO: Well you didn't start in the inspections.

SL: Oh no. I mostly fraternized with inspectors.

RP: I think that was an interesting time, Sterk, because you came in as the first management . . . What was your exact title?

SL: Management assistant.

RP: Assistant. But at that time we changed the management part of the districts. We used to have a chief clerk, and then we went into having management assistants, and you were the first one in Chicago. And I don't know whether you have any comments on that particular change in the way FDA . . .

SL: It was tough on me because the entrenched administrative assistant resented moving somebody in over her.

RO: Who was the administrative assistant?

SL: Alice . . .

RP: Alice Brookewood.

SL: Brookewood, yes. And I think after about a year she found out that I was relatively harmless, or could control me--I don't know which it was. (Laughter) I guess we got along after that all right and then she left, retired a couple years later.

RO: Well how long were you in Chicago?

SL: Nine years.

RO: Nine years.

SL: Yes. After I think it was three years I got converted to administrative officer and did some good things.

RO: What were most of your duties as administrative officer in a district?

SL: It was management of the finances, the personnel, the records, the procurement, I guess a lot of the maintenance ordering. And I got into work planning, which was always of interest to me. I went out on a lot of road trips so I could gain some credibility with the brethren in the investigation force.

RO: Well how much freedom did the districts have in their own work planning?

SL: They had a lot. I mean, if your manager wanted to have freedom, he'd do anything he wanted. There was guidelines from headquarters, but they only planned about maybe a third of the time with any specificity with the compliance program. Each manager was responsible for knowing the problems that were specific to his own area and was responsible for covering it. Once they took care of their obligations under the national plan, they had the rest of the time, or about two-thirds, to handle things as they saw necessary.

RO: Problems that were unique to their territory. And you were there, then, for nine years, and then what happened?

SL: Then I had, I guess, the need to move on and have new responsibilities. And opportunities came and I went on a detail, I think a two-weeks detail, to a place that I applied for a job. This was . . . I get . . . It was still the program analysis branch, I believe.

RP: Probably.

SL: DFO. No, DPO, Division of Program Operation.

RP: That's right.

SL: And they're the program analysis branch.

RO: And this is in headquarters in Washington.

SL: Yes. No, it was in Virginia, Crystal Plaza. And I think shortly after I got there they changed it to ACFC, Associate Commission for Field Coordination. It was still in Virginia, and then we moved up to Rockwood.

RO: Now you said you went on a detail . . .

SL: Well, it was a detail to the same office but program operations.

RO: You really got transferred, though, from Chicago then to the headquarters.

SL: Right.

RO: And that was in, what, 1968?

SL: Sixty-eight, yes.

RP: I think that's right. We were in the Division of Program Operations and then . . . What year was it you came in?

SL: Sixty-eight.

RP: See, it was the Goddard reorganization then that put us under the ACFC.

SL: It was Sterk and Cork . . . (Ed) Tuerk and (Eric) Storck, I guess it was. Those infamous names.

RP: Well, yes, we . . .

SL: And then we reorganized into EDRO shortly after that, I guess.

RO: When you came in then, was there a bureau that you reported to?

SL: Yes, Bureau of Regulatory Compliance.

RO: That was when (Inaudible).

SL: (Inaudible) program office.

RP: Under Al . . .

RO: Barnard?

RP: . . . Barnard was the bureau director. And the division director was Doug Hansen. And that was Division of Program Operations and we were the . . . Were we called the what branch?

SL: It was Program Analysis.

RP: Program Analysis Branch. I happen to have shared that lifestyle with Sterk in those days.

SL: Yes, after donating his office to me out in Chicago and not forgiving me, he forgave me.

RP: He mentioned back in Chicago that the clerks tended to resent him, and I wasn't going to say it, but some other people resented him, too, in those days.
(Laughter)

RO: Including yourself.

RP: Including me. (Laughter)

SL: (Laughter)

RP: But I, you know, I changed my mind. I learned better.

SL: He overcame.

RO: Well I was interested because at that time I thought that the inspectors did their own planning, and the laboratory did, and I didn't think it was centralized to the point of the administrative office really doing the planning. Early on.

SL: Most places it wasn't. I mean, I got into it three years after I got there because I was interested in it.

RO: You thought you could do a better job than they did.

SL: No, I really was just trying to help, because the supervisors had such humongous groups to supervise. You know, they were, you had about thirty-three you would supervise at that time?

RP: Yes, at the time you came in I was the only supervisor in Chicago, and I had everybody, really. It was a difficult situation, because you'd have one chief inspector and one supervisor. I think in some districts they divided up the work. In Chicago it really didn't work out that way, in my opinion.

SL: The chief inspector was the figure head, and the supervisor did the work.

RP: And Sterk had a particular interest I think. I doubt if the people that had his job around the country for the most part had that kind of interest. So I think he was unique probably in that. Of course, gradually that changed. By the time you were in Washington, there were years when we had the management person in charge--whatever their title might have been--from the districts came into our work planning strongly. Isn't that right? Or am I wrong about that?

SL: I don't know. A few districts.

RP: A few districts.

SL: Most of them.

RP: Okay.

SL: Mostly because the administrative officer people that replaced the first group of management assistants weren't, in my opinion and from my knowledge, were not educated in any of the management sciences. Usually the best (Inaudible) in the district earned the trust of district directors who themselves had very little management education.

RO: Then your first job as you came into headquarters you said was in the analysis part of the organization.

SL: Well they did the work plan, too.

RO: They did the work plan.

SL: The program analysis branch.

RO: But you actually did the work plan.

SL: But it was . . .

RP: Well, and we did the work planning and we were in charge of . . .

SL: Budget.

RP: . . . the field data system.

SL: Yes.

RP: And the field budget in the sense that . . . You know the budget branch has always prepared the budget. We didn't literally prepare the budget, but we prepared the background information, and they did the wordsmithing was I think pretty much the way you might say it. And, you know, there were young lads in there doing that like Ron Chesemore. (Laughter) So we really had a broad, a lot of things that the name of the branch didn't encompass.

RO: Well it didn't seem to me, because I was out in the field at that time, that you had the, I guess, sophisticated planning that they did in the later years from headquarters. Because I remember when Al Barnard and you mentioned Storck, they had planning sessions, Eric Storck, when the field actually had to prepare their own work plan.

SL: When Goddard came in, under Storck and Tuerk, they did a lot of things. They destroyed the field organization and replaced it with ACFC (Assistant

Commissioner for Field Coordination) which was a one-man operation. And they did other things, like they made each district an independent Food and Drug Administration. From our standpoint, they destroyed the OEI (Official Establishment Inventory) more or less by going from a five-digit body code which meant something to a two-digit industry code. So we lost pretty near in one swoop the information about who made what except in a broad sense. And at the same time, the planning from headquarters dropped to loose guidelines, I believe.

RP: Right. What Goddard did was to make each district director, to change it so each district director reported directly to him.

SL: Yes.

RP: And everybody else in headquarters that dealt with field matters in any way became strictly staff. We lost . . . Well staff has always had some line responsibilities, but we lost anything of that nature. So all kinds of continuity was lost and . . .

SL: And DFO (Division of Field Operations) continued to exist, I think. I remember, because we were sort of reorganized into a program evaluation group and a program planning group. I got I don't know whether you'd call it stuck, but under

. . . I'm trying to remember the guy's name that came to work from the Defense Department--Carmen Soviero. And that only lasted for about six months, and then they just broke it all apart. A third went to the new reorganization; a third went to assistant commissioner for planning and evaluation; a third, including me, went to EDRO (Executive Director of Regional Operations); and a third went elsewhere.

RP: To the bureaus, some of them.

RO: Well that must have been in late 1969 then.

SL: Yes.

RO: Because that's when Sam Fine took over DFO. Is that right?

SL: Yes, I think so.

RP: Just about. You remember . . . Who did we work for when we first went into . . . ? Who was the ACFC?

RO: Harris Kenyon?

RP: Harris Kenyon.

SL: Yes, right.

RP: When Harris went to the CPEHS (Consumer Protection and Environmental Health Service) and lost out all of his opportunities in FDA, and by then Sam Fine came in as ACFC, but only briefly before they made that into a real job. That was after Goddard left. I've had occasion to read the interview made of Goddard in 1969 shortly after he left FDA, and he tells about those days. I think he said he had, when he did this, he ended up with something like thirty-eight people reporting directly to him and that that was no problem as far as he was concerned. I just throw that in because . . . But it did . . . It was a confusing time, and it was a time when we . . . And we had been operating under George Larrick for years, and you sort of knew which way you were aiming and what was expected of you, and suddenly we were all thrown into turmoil, which wasn't all bad because we had developed . . . There's no question in my mind that the fact that FDA was pretty ingrown was really true and that we needed some shaking up. But for those of us there who were at the epicenter (Laughter) of that shaking up, we were shaken up.

RO: Well then you said you came to the EDRO organization, which is the Executive Director of Regional Operations. I don't think that was established until really in 1970 when Charlie Edwards was the commissioner.

SL: Yes.

RO: And I think Sam Fine had been elevated to the associate commissioner for compliance, and Paul Hile came in then though as the executive director of regional operations. Now in the EDRO organization, what position did you have?

SL: Well I was a program analyst until '72, and then they broke the branch up, I guess, reorganized and made two sections.

RO: Well who did you work for then?

SL: R. G. Porter.

RO: R. G. Porter.

SL: Esquire or whatever.

RP: See after I left in '72 they straightened things out a little bit.

SL: It seems like you left about five years ago, but . . . (Laughter)

RO: Well that was a division then before the . . . Right?

SL: No.

RO: Well when you worked for Bob Porter, that was a division?

RP: Well, no.

SL: No, the branches were graded as divisions, and the sections were graded as branches, but it was . . .

RP: I was the acting division director for a year before I went to Denver, but they didn't divide that branch into formal sections. When I had the branch, all the program analysts worked for me. They had . . . Obviously different ones had different responsibilities, and I think Sterk very quickly got into the planning, I think. I don't mean to put words in your mouth, but I think that's true, if I recall.

RO: Tell me a little bit what the planning really constituted then as far . . . You said at one time it was rather loose. It was only about a third that was controlled from headquarters.

SL: The planning at the time, what we did was plan 100 percent of the field resources but received guidance from the centers, from the compliance programs that were existing at the time, that covered about, I would say, 30-35 percent of the field resources. We would have guidance as to the overall program, breakup of the resources: how much foods, how much drugs, and etc.

RO: Where did that come from?

SL: Well even then it was based on the budget. Everything has always been based on, since I've been here, strong program budgeting.

RO: Did the EDRO organization have any input into the budget process?

SL: Yes, very much I would say. We were the only organization that had our act together I would say, because we had a lot of experiences, people who had been with the organization for a long time and been in planning so that they could view it in its total context and put it all together. And we ended up, from that time on for

about fifteen years at least, we would always do Bureau of Veterinary Medicine's planning, because they never could come up with it. We always worked very well with Foods, because they had a good group of people that were experienced. It was just before that we--what was it?--the Bureau of Science and the Bureau of something else combined into the Bureau of Drugs, and shortly afterwards they added devices and biologics. And we had a lot to say on the planning with those, because they didn't have any experience either, but they eventually got (Inaudible) up pretty quick.

RP: Excuse me. You said we did their planning. You're really talking about we did what they were supposed to plan for the field.

SL: Yes, yes.

RP: I didn't want it to be understood that we were planning what the bureau itself did. It was what the bureau was setting up and expected of the field. Wouldn't you say . . . Ron asked you if, you know, where did the direction come from as to how much we put in this and that. Wouldn't you say that it wasn't so much that it came down from on high, but that you would sit there and, using the budget as your guide, you would really prepare something which went up for approval?

SL: Right.

RP: But the actual plan literally started on your desk in the sense that, while you didn't have the last say, you gave them the things that the people on top reacted to and approved.

SL: Right.

RP: And usually approved it without change, or very often.

SL: We began to get our recommendations right in the budget process so that when we asked for new funds, we, EDRO had its say right from the start.

RO: From a program standpoint as well as a resource one?

SL: Right.

RP: Wouldn't you say that we were the only people who could, because of our data system, we could transfer programs to resources. We could turn the things that a program wanted done into man years, and I don't think anybody else in the organization could do that except just . . .

SL: Early man, manpower management system.

RO: Well as that came down from on high then, you'd get resources for the field. Was that broken down by region or district?

SL: No. No, it was broken down programmatically and in broad terms with foods, drugs, and other things. And the budget would have some commitments in them to Congress about we were going to increase coverage of this industry or address that problem more specifically or intensely. And then we'd translate it into more discrete programs that were assigned work loads to the districts and operations to the districts based on their work load, which was industry and other things like population, and crop production, and pesticides, and things of that nature.

RP: You did this program by program, didn't you? Because in one program New York district might have practically no work load and Denver might have a big part of its work load and then vice versa on a different program.

SL: The work and resources were assigned based on their portion of the work load. I don't know exactly what happened, but when we switched to the project management system--I don't know if Bob was still there then or not, but I think you were there . . .

RP: Yes, I was there.

SL: And that's where we switched from the . . . We were very instrumental in forcing the system to cover 100 percent of the resources, and that may have hoisted us upon our (Inaudible), but we felt that we ought to have the centers provide guidance for all of the resources, not just for a portion. And the guidance, of course, in our terms didn't mean controlling guidance but more program guidance. We, for several years and several instances later, had problems with the centers trying to assume too much control over field activities. But . . .

RO: You mentioned some trouble. You meant by the precise number of inspections on concise number of samples that were going to be analyzed?

SL: Yes, and they even with completely inadequate data were trying to focus it on certain areas of the country and for no reason basically. And whenever we would disagree with them, we would have facts and they wouldn't, so they would back down.

RP: (Inaudible) made a comment on this, Sterk. Some of that change was just plain political. The bureau directors, once we went to the Bureaus of Foods and Drugs, those people came in and thought that they were in charge of the entire food program of FDA, which of course was, a very substantial part was field, and they felt

that they should run the field. And by telling them they could plan all of the field work, it satisfied politically a need, and I don't think it changed too much what came out at the other end of the pipeline as far as a plan is concerned.

(Interruption)

RO: Well now when you got the cut of resources, the programs that the agency was going to do, that was approved by Congress. A certain percentage of resources were going into this . . . What if you got into a big emergency and you had to divert then to a food program or a drug program, could you alter from that?

SL: No, it was with full knowledge that we're a fire fighting agency that we had to address the problems of the moment. We always publicized the fact in our plans to, in our narrative discussions with all the field management that a plan was a plan and is a logical way to assign resources and located around the country to handle problems. And it was local management's job to manage those resources and address the problems as they came. If there were no emergencies, then they were expected to follow the plan as close as they could. Lots of times they would have hiring problems and couldn't meet some of the plans, or they had too many people compared with what their share would have been ideally, and then they would accomplish more work in areas that they thought were important.

RO: Sterk, you mentioned 100 percent planning of the field resources. Now that meant if you had, you know, fifty inspectors, all of their time was planned. How did you determine exactly how many inspections they were going to make and . . . ?

SL: It all went back to our what I call our manpower management system, which is now politically correct to say work force management system. The data system provided historical data on what we could expect as our average production from each position class. When we had a total time system, the T & P system (time and production system) in my opinion, we were as close to having adequate data as we've ever been. And I wish we would have improved on that as a basis instead of flipping over to this program-oriented data system, because instead of improving on a system that pulled in all of a person's work, it just focused on a little over 50 percent of what they did. And that allowed the accurate accounting for time use in different areas to blur, I guess you would say, because if you don't have to account for all of your time, then what you happen to be thinking about at that moment either gains more or less importance than it really had. Also the switch from industry and product-based problem solving to . . .

RP: To problems.

SL: Yes, problem solving I think was a disaster, too. I lived with it for many years, and it's always been difficult for people . . . I went out in the field all the time trying to improve communications, and down at the base level of investigator, he's not going out and inspect a salmonella plant, he's going out and inspect a peanut butter manufacturer. And I think we should have built on the industry orientation and product orientation and superimposed the problem collection data on top of it.

RP: Why didn't we? Why didn't we go that route?

SL: Well I think in retrospect I think it was all the new wave of management that came in. I guess it was Goddard's time and Storck and Tuerk.

RP: Don't you feel that it was probably a result of the Booz, Allen and Hamilton study? Now I don't know . . . Were you there when we were doing that?

SL: Yes, and you know, I saved that for many years, and in fact I still have one pristine copy in the archives left, but they were operationally oriented as I recall.

RP: They were.

SL: And that could have been . . . That could have worked into our system . .

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RP: It was operationally . . . Well, we had . . . There had to be some reason we went that way, and I can tell you now that that wasn't me. (Laughter) I was interested in, I would have gone the way that you just suggested of retaining the T & P system as a, developing it, amplifying it, and making it do what we wanted to but still using it as the way we went about things. And I can tell you now it was at least partly due to Booz Allen in that Booz Allen was not interested in collecting data except on certain operations, key operations, so that they were against the total time system. That was one point. And the problem-oriented thing came from Tuerk, who was the assistant commissioner for planning.

SL: See that was (Inaudible).

RP: Yes, it was, but these were influences that we had to react to in devising the pods, the new data system.

RO: Yes, but with scarce resources, wouldn't it be incumbent on us to look at the problems we had rather than . . .

SL: But still, when you're addressing the real world after you've prioritized your problems, then you need to translate them back into the real world, and that's where we failed. If you're going to handle a perceived major salmonella problem, that's fine, but then in your planning to handle it, you're planning to cover the industries that have the problem with salmonella. And that's where it fell apart.

RP: And I think this was because of a misconception on the part of people above that a problem was in a sense industry-wide, and there are very few problems like that. Most all problems turn out to be problems that involve one, or two, or three, or, you know, four industry groupings, but not everything that you're doing. And I think Sterk's expressed it just right in my opinion.

SL: What are you doing today now? Well, of course, you've retired, but before you left, as far as the system is concerned. Has that changed any in the last number of years?

RP: We've got more technically able. We can do everything faster. I mean there's . . . I don't know where it fits into the discussion, but the work plan itself is more . . . It's made more quickly; it's more accurate. We get a lot of feed in from the district offices that have a number of times to react to preliminary plans and final plans, and we can make the changes quickly that need to be. We can start the work

plan pretty near within a week or two if a commissioner comes down with a new initiative. We can get it out to the field, where we used to have to send them out a telegram or something like that and say, "We've got a new problem. Do the best you can and we'll follow up with a work plan later"--much later it was.

RP: This is because of the use of computer technology?

SL: Yes. I had . . . There's a number of ways to go about this remembrance. When we computerized, that's probably another whole story. But shortly after we turned into EDRO we brought in--I guess it was Storck and Tuerk's group brought in--some consultants. I guess it was (Inaudible) Jake Barkdoll had just got in, and between him and I don't know if it was Bradley Rosenthal (Inaudible). It's a little blurry in my mind.

RP: It was Bradley.

SL: And so they got a consultant group to try to computerize our work plan. And I was there of course and leaped in with both feet. I can remember when they were there the last year I put the work plan together on a project basis for the first time using hand spread sheets, calculators, and green eye shades and all that sort of stuff. The next year was the first year that we had computerized backup, and it was actually

the computerization of our hand . . . It was literally automating the spreadsheets that we had used. I mean the system has always been the same. You have a basic formula. You have an operation to do, and how many of them, and how long does it take to do each operation, and that's like the basic building blocks.

RP: Do you recall . . . Maybe it's the result of the group you just spoke about, but do you recall for one or two years we actually had the plan on a computer with a company that worked out of San Francisco?

SL: I'm sure . . .

RP: And that was our first time share.

SL: Yes.

RP: That was our first experience with the plan on a computer.

SL: And then they did it on our in-house computers, the mainframes, and then probably about five or seven years later it was rewritten to be handled on our mini-computers, (Inaudible) John Lechus and another . . .

RP: So you did it in your own office at that point?

SL: Yes. And we didn't have PCs until I think it was about 1984, something like that. The first PC we had was we had these terminals, little video terminals, VT 180s, or yes, something like that, VT 100s. And they were hooked into the mainframe and then later back into our computerized plans via those things and print them out in the printers.

RO: Now the mainframe--you mean the agency's mainframe or . . .

SL: Right, the IBM mainframe.

RO: I see.

SL: And then I think putting the managers together at the time, I think this was by the time that Hile had left, and (Don) Healton was there and they brought in Herbie Klein, who's another story, although I got along with him fine, but I, you know, he destroyed a lot of interpersonal relationships in the agency (Laughter) and they took years to reform.

He and myself somehow were reading about how you could take one of these monitors and add a little, open it up, and make it, put a little central processing unit

in there and make it into a little personal computer. It was called a VT 180, and DEC (Digital Equipment Corporation) called it a robin, I guess, because you had to have a little name for things like that. I think about the same time DEC had come out with Pro 350, which was a laboratory PC that was used in analog work tied up to equipment and then sort of harnessing that for developing data. And they bought us one of those before, I think, the VT 180, but it was a dog. It was slow, and they had some terrible software on there that was so convoluted that you couldn't . . . I mean, it took more time to do everything on it than by hand.

RO: DEC, you mentioned DEC. What is that?

SL: Digital Equipment Corporation. All our minicomputers were those. And of course the guy that ran the data processing, (Inaudible), was later found to be in bed with DEC, and summarily not punished too bad. If it had been me, my head would have been blown off, but not (Inaudible). Anyway, the little PC outperformed that 350 by leaps and bounds, and that was it, and then we got, DEC came out with a very nice PC later called the Rainbow, which was technically much better than IBM PCs, except that it had a slightly different operating system that didn't catch on. So we were forced to stay with them for probably a year after we should have switched away from them, because the same computer management group wouldn't allow . . . Control took in a little (Inaudible) with DEC stuff. And then later, after much

blood was shed, we broke out of that and got IBM compatibles, so from then on we were at the front of the pack, because we were where the money was and we had two people . . . Myself and John Lechus were very technically oriented. We knew the best that was available and we got it. We did the extra work to find out how to get it, procure it, and get through all the maze, so from then on we always had the best.

RP: So you were pretty much independent then of any main computer, is that right? You did most of this right back and . . .

SL: It was all on our DEC minicomputers, and a lot of the stuff we were . . . In the last years I was able to put all of our manpower models on my own PC and the other people in my group so we could react to . . . When I'm talking about the manpower model, that's an adjunct to the planning model where we translate everything then to tables of organization and detailed staff increased district.

RO: How do you go about that?

SL: Well, the work plan as we designed it, right from the start when we first automated it, was two systems of models. One was . . . (Background noise)

RP: We're getting a little competition.

(Interruption)

SL: The planning models, the system of planning models included two general orientations. One was for the actual operations that had to be done to accomplish the year's work, and then we also had a backup ancillary system that translated each one of those operations into the number of people that were needed to do the operation.

RP: And the kind of people.

SL: And the kinds of people. And they were always absolutely integrated with each other, so each hour that you would plan to do an operation was supported by an hour of a kind of person to do that operation. And then when we got the work plan all done and all the work assigned to all the districts finalized, then it automatically created a table of organization that took the operational people needed to do the work plan and supported them using ratios that treated everybody the same. You get so many supervisors per number of investigators and analysts. And then you would add the organization hierarchy on top of that, the branch director and secretary. And depending on the size of your operational groups . . .

I guess I have to recede back a bit, but the Compliance Branch was the third branch, and that was . . . We had originally used the logic to staff them based on the

amount of investigational work, both domestic and import, so that if you had a bigger district, you'd have more compliance officers. But that was . . .

Compliance officers in the field, their work loads, in my opinion, defy rationality. And the district managers didn't like that, so lately we tried a number of different ways to staff the compliance offices, none of which were very popular, and then they had a work group of district directors and a few Compliance Branch directors that . . . I think Dick Davis was one of the main, the leader of that group, and he was oriented more or less the way we were, that you ought to have some kind of a work load. So they, with our division's help, got a lot of historical data on compliance actions and other things they thought were needed and figured out how many people would be needed to handle that number and then spread it by district based on the number of legal actions. Well, they came up with a number of you need something like sixty-two compliance officers, and my God, there was ninety-two on board. And so they just said, "Well, we can't have that," so they just, "Wow, let's spread it by, prorate it up to ninety-two." And it was a sad . . .

RO: It was rather an arbitrary cut then.

SL: Yes.

RO: Now when you say operations, depending on what kind of an operation it was, that would require a different expertise in the field wouldn't it? As far as an inspector or an analyst?

RP: I think that needs more explanation. Elaborate a little bit on how that happened.

SL: The work plan was capable, is still capable, of planning operations into a number of different specialties so that in an investigational side you can have technicians, or I guess we call them inspectors now, and then journeyman investigators, and investigational specialists. Later we added specialists for new functions that the agency picked up like food, milk and food specialists that worked with state programs, shellfish specialists, radiological specialists that worked again with states on their programs of radiology. The specialists were further broken down at one time to say like you were a drug specialist or a food specialist, microbiological inspectional specialist, and that was . . . The same in the laboratory. We would tell them how many pesticide chemists they would need who would specialize in that, drug specialists, aflatoxin specialists, how many microbiologists. This was used by the districts to get higher grades justifiable to the personnel offices. That ran for about ten years, and then I guess most of the battles ahead were personnel-abated so the need for that support dropped. So when I left the work plans probably for the last

five years, even though we had a lot of that data available, wasn't needed so it was not published.

RP: Sterk, just to go back again, would you give us an example or two and tell us . . . For instance, let's say that through the budgeting process and then the work planning process you've got a district that has to make an inspection of a drug plant. How does that . . . And that's the given, sort of. How did that translate clear down through into pieces of a table of organization?

SL: Well each operation has a historical amount of time to do it, and we know what kind of a position we need to do the job. So that segment of time is added together with all the other time needed to do inspectional operations. And this is all summed in the cross programs and then converted into person years.

RP: So you know, for instance, that this drug inspection, historically an inspection of that order has taken twenty hours of investigative time, let's say. Okay, now what next? Now we've got twenty hours of investigator time, how do you know where else it takes to do that job?

SL: Well, through our historical data, which got less and less encompassing over the years, we knew that we needed backup time to do that. The time reported to do it . . . An investigator . . . Is this what you're leading to, I think?

RP: I think so.

SL: An investigator doesn't do inspections all day long. He has to improve his knowledge of things by reading manuals and administrative things out of training. Travel is another thing that stacks on. So that after we determine a number of hours, again through historical data, that it takes to do all the different jobs, we then have to build in time to get the person trained and out to do the job and also set aside time for leave and holidays and administrative work. So we used a conversion factor--what those in the trade call it anyway--where if you had for every, say, 930 hours of work that you planned, program work you were assigning to an investigator, you had to set aside time also for work that you weren't planning but had to be done. Is this coming in over the mower?

(Interruption)

SL: All right, historically the way we used to, the plan worked was that we knew that when we went out and did a, say, a food inspection that on the average we'd

collect so many samples--a lot of them on line and a lot of them finished products from other sources that had to be analyzed to back up the inspectional data. And so we would plan for every inspection to collect two or three samples, and then that in turn we'd plan to have each one analyzed one or more times. And that developed a need for planning . . . Well, first of all, the sample collection work had to be planned separately, so that had to be staffed. And then all of the analytical work is what drove the need for laboratory staffing. The laboratories all had . . .

(Interruption)

SL: The laboratories also had work needs based on research programs that were centrally driven, and we also added time for applied day-to-day research to help their own problems that they ran across. If there were no methods that were available that they had had to develop on the spot, time was built in for that kind of research, too. And then there was also time built in for other quality control work things like equipment calibration and, I guess, media preparation. But back to the investigation, once you get the work plan work planned for and the different branches to support it . . .

I'm a little disjointed here, because I started going into this in the table of organization which handles a lot of that thing. The total number of investigators that comes from the need of the work plan is first of all what we call translated into a full

investigational person here. And the work plan for investigators actually only covers about 900 to 1,000 hours every 2,087 that a person gets paid for. We also know from the historical data that they do a lot of operations that we can't plan for individually, like evidence development that's outside of an inspection, special investigations, court appearances, things that are programmatically related. It's just that we don't know how many emergencies we're going to have, or we don't know how many bad parts of industry we're going to find, and so we just set aside time to cover those things based again on how much we've used historically.

So that gives us a total programmatic portion of the investigational work here, which is about, I'd say, about 1,200 hours, between 1,100 and 1,200 hours. And then we add, build in time to travel which is between 200 and 300 hours, and then also the rest of the paid person here is administrative time and leave and potty breaks and stuff like that. So we know exactly how many full investigators it takes to do the amount of work, and so we can translate it into that. And we do the same thing in the laboratory, and then we support all of those with administrative positions, supervision based on ratios that have developed historically.

And then the administrative office, which supports all the other segments of the district office, is based on a number of different factors. Some are every district has to have an administrative officer and a procurement clerk and things like that, and the rest of the positions are based on the size of the district that they serve. So a small district would have, with all of the support, would have relatively more

support percentagewise than a very large district because (Inaudible) scale (Inaudible).

RO: Well now this is for the districts. But we've got regional offices. How does a table of organization get developed for the regional office?

SL: Well the regional offices, theoretically, we have split them into two groups. We have a management group and a program group. There's many . . . Most of the state programs that we administer are located in a regional office in what we call a state services branch.

RO: Let me interrupt. What do you mean state programs?

SL: These are the programs that we picked up from the Public Health Service when we were merged into the Public Health Service. It's milk and food sanitation, shelter sanitation, radiological health work. Since . . . Well, I don't think much of the regional structure neither historically (Laughter), because when the regional offices were formed--to digress a little bit--that was a politically correct thing to do at the time. From my perspective, what they did was take about a hundred people out of production and constructed a regional hierarchy that wasn't needed and was probably counterproductive.

RO: For political reasons.

SL: Yes.

RP: Strictly political at the time. I was there.

SL: And it took a hundred or so people that were dedicated and operating as consumer protectors right out of work, and it just . . . It was wrong. Anyway, what were we talking about? (Laughter)

RO: I guess we were still back on the table of organization, and I interrupted you and asked about the regional office.

SL: And then since we constructed that useless hierarchy, in my opinion, we also wanted to have a staff of people that could provide the types of support and services that we provided the EDRO and later the . . .

RO: The ACRA.

SL: . . . ACRA, whatever it is, for the regional director or the district director. So we staffed each regional office with people that they could use for program analysis

kind of support. And the regional directors had the option of keeping them at the region in the staff there or decentralizing them to the district offices where they'd work for the district director. We, of course, recommended that they be put in the districts to start with, but the prevailing political correctness at the time was that we had to give the regional director the option because he was stuck in with managing the region. So that had some sense in it, so we didn't keep fighting. And some districts did decentralize and it worked out very well, and some kept it centralized and some of those worked out very well.

The table of organization was always, had the regional offices in most regions staffed at much less than what they had. The regional directors, some of them built empires and took positions away from the districts to staff them higher than headquarters gave them.

RP: But they did have that prerogative if they saw fit.

SL: Yes.

RO: Well at one time there was what we called single district regions. But then with the change in the regional structure which took place when, what year? About 1986 or '87, somewhere in there?

SL: Yes. It was . . .

RO: That eliminated single district regions.

SL: Right.

RO: Every region now has more than one district, isn't that right?

SL: Right. That in itself is another story. I worked on that.

RO: Sterk, let me ask, you mentioned early on here about T & P, which was time and, what, production (Inaudible)?

SL: Production.

RO: And that was almost a total time as far as the operational people in the field. And now you mentioned then the different operations or activities that an inspector performs and the chemist performs, and do you capture all of those activities on the data system, or how do you do that?

SL: Bob covered a lot of that when we had the T & P system and the . . . What did we call that spreadsheet?

RP: Four eighty-one?

SL: Yes, 481. And those things never (Inaudible) totally, but if you knew the differences and were careful how you used the data, that was pretty good. But then when we went to the new system, I think right from the start it only reported just the program operations that we thought we could actually report on and have some credibility, and all the other work *could* be reported. All program work could be reported, but things like investigations and things like that became very nebulous because there was no count out we could . . . You couldn't count them, more or less, because you never knew when they ended. Sometimes you never even knew when they began until after they'd been going on for about three weeks or something like that. But if you had had a total time reporting system, those hours would have been reported as an investigation, and you wouldn't have to have it formalized.

RP: Frankly, in the early years after we had left the T & P system, we still went back to it to determine approximately how much of these non-operational hours on the average were spent.

SL: We used those as a background for probably ten or twelve years, and then we finally had what we called a total time study done where each district had to report everything that they did hour by hour for two months or something like that. Then we sort of used that as our new guidelines.

RP: You know, what's interesting about that T & P system, it was a total time system, and I could, at the end of a year, from that system I could figure how many inspection hours we had put in, and convert that to man years, and walk down the hall to personnel who kept average man years--now they call them . . .

SL: Person years.

RP: . . . and I've known years when we were within one man year of each other when we're talking about quite a few man years. That doesn't mean it was right. It means it was consistent with the number of people.

SL: Once you take the total time out and you just allow all sorts of abuses. I had people in to my office and details that would tell us that their supervisor would say, "I don't want you reporting any more than twelve hours per inspection--that's what the work plan said. Even if it takes fifty, I don't care, don't put it down." And then

there'd be other times when, "Report all the hours you can, because we need to have accomplishment data." And you know, it's . . .

RP: But these were true . . .

SL: (Inaudible), yes, but it was . . .

RP: This was true, yes, because, you know . . .

SL: . . . but since you didn't have a total to reign in credibility somewhat, under the new system we found data from when the compliance officers were reporting. A guy was working on an average something like twenty-four hours a day--he never slept, he never did anything. This was an Atlanta specialist. And what the hell's going on here, you know?

RP: You'll always have . . . I don't care what the system is, you'll have problems like that.

SL: Yes, but if you have somebody watching it and monitoring it, you'll (Inaudible).

RP: Yes, but they manage it. They don't just monitor it for the truth, they manage it so that it has the outcome that they want it to have, and they always will.

RO: You mentioned a 100 percent plan, that the work force was 100 percent planned. But really there was flexibility then depending on this inspector module or analyst module that you're talking about. Was that every challenged by the centers or the bureaus?

SL: Yes, quite often, because their own planning systems are so . . . And they don't have to account for pretty near anything in their own offices, and they count everybody that shows up for work as a worker. So we segregate ours into plannable units and talk about . . . We change the word from support to program direction and assistance to get away from a lot of the criticism. Because when we had these dialogues with them we could more easily talk with them and say, "Well, look, you don't count . . . You have this office of compliance, and you count them all as productive, but you've got directors and secretaries and data entry people that you're counting as productive that we don't count as productive." So by laying it out in detail and being willing to talk with them, I guess we satisfied most of the criticism.

RO: Now when you developed this work plan for the field, you go back to the centers now then and negotiate this or is that fait accompli when you . . .

SL: No, that's a iterative process where we've been working with them on long-range planning, budgeting all along so that all of their, all of the new program initiatives have been agreed upon between us. We have a lot of disagreements, and in my long history we have had . . . Everything that's going above us for solution, I would say that we won probably about 99 percent of the disagreements.

RO: When you say "go above" that means up to the commissioner's office?

SL: Well, like sometimes ACPE (associate commissioner for planning and evaluation) or the planning office, the agency planning office, sometimes the budget office, and sometimes all the way up to the commissioner's office. And again, usually it's because we have ample information to support our position and the centers had some other reason to purport saying those things. So anyway, we work with the centers on the work plan after, and sometimes at the same time we were doing the budgeting all the way through.

When we first started the work plan the year before the issues to the field, we issued what we called a call to the centers saying, "This looks . . . This is how many resources we have now in your program area, and it's clearly ORO's resources, not the center's resources. And they were using them to support the program areas that had been providing guidance, and this is the breakdown of people we're using to do these current jobs, and this is what's available for you to plan." Now we don't plan

on getting any increases or decreases at this time, because you can't count on the budget entries until many times after you get the plan issued to the field, and by then it's too late to hire people to do much of anything.

So what they do is have an internal, the centers have internal programs they use and they decide within the center what new program directions they want to go in or shift to and provide us with a preliminary forecast of compliance programs they want to have carried out the following year. Then we have a chance at that time to, well, responsibility basically of reviewing it and take an issue with things that are wrong or supporting things that we agree with. And then the field offices also have, we have a system where the second we get that we ship it off to the field, and they have a full chance to become involved in that process of critiquing what the centers have outlined as their plan.

The first critique is done by field committees, and they get together and look at it and come back with their comments about these plans, and then we get back with the centers and share that with them. Either end . . . I mean, they have committee meetings, the field committee meetings with the center and staffs, and we also work with the center planning staffs and budgeting staffs to make sure that nothing falls through the cracks. And then they digest that in the centers. If we have any disagreements, we usually work it out right there, and then we come back with our final forecasts that now meet the restrictions of available resources, and we translate that at that time into allocations to the field offices. In other words, this

is what the centers want to do in these program areas, and the way we, your share of the inventory means that you're going to get this much of the resources. It's like a preliminary work plan. We send that out to the field offices.

Over the years we've done that in a number of different forms, and some years . . . (Bird caws) Good background! (Laughter) Over the years sometimes we've run afoul of timing where we didn't get information in time to get it out to the field and the field officers in a preliminary form. But we all always in our system, even after the final work plan is issued, the field officers can have a formal or informal process what we called the 17B process, because it's easier than . . . That's a field management directive that explains that they always have the duty and the facility of being able to comment on the work plan and get them changed, the work plan changed if it needs to be changed. The work plan is not supposed to be changed month by month so that the end of the year you did exactly what you planned. But it should accommodate major shifts or mistakes.

RO: You mentioned a while ago, Sterk, early, in fact, the OEI. Just exactly what is the OEI?

SL: The OEI is the official establishment inventory, and it's only official because certain managers at one time wanted to call it official.

RP: I called it that. (Laughter)

SL: We're one of the few agencies that don't have a legislative charter to keep information about the industry we regulate, and it blows my mind. And since we don't have that, we've had a long history of good starts, and stops, and then malaise, and neglect, and then good starts and . . .

RP: And fast starts, too.

SL: Yes. And that's one of the high points of my career: I finally got that institutionalized I believe, I hope.

RO: Well now, there are a lot of births and deaths in the industry. How do you keep this current?

SL: Well the OEIs are based out in the district offices. It's a data collection system where each district is responsible for knowing the establishments that need to be regulated. Since there's no legislative requirement or regulatory requirement that food establishments report to us that they're in business, we have to pick up the information as we can get it. We get it through surveillance. Investigators when they're inspecting another establishment they'll see something that they don't think

is in our records. We have agreements with state regulatory agencies that do have requirements that places register. Our drugs and devices and veterinary drugs are required to register with Food and Drug Administration, so we get the birth information through those systems, although they can be out of business for several years without us finding out about it.

RO: The deaths don't have to be reported.

SL: Right. So it's . . . I'd like to have food registration. It's been proposed several times, but there are so many very small food establishments that I guess the small business costs would be so much that it is not politically correct to get that done.

RO: Well now what is really in the OEI, because there's a lot of businesses within . . . Is that just those that do interstate business, or is it . . . ?

SL: Yes, we have to have . . . They have to do interstate business if it's foods or if it's drugs or anything else. It doesn't matter. And some of the veterinary work, I guess, is non-drug. That should be interstate work. And that represents only about 60 percent of our work load, these establishments, because we have import work which takes about 30 percent of our work--25 to 30 I think now. And work we do

that's not establishment based, like pesticide work, microtoxin work, anything based on crop production or acreage (Inaudible). So we have a lot of different work loads, but the OEI is our primary workload. The need for accuracy in terms of knowing an establishment exists is paramount. Our whole enforcement structure is built upon that, and we found out that our data over the years was not very good, and we'd try to do some things about it, and it's work. It's work that takes people out of production, of investigations, because a lot of those people have to do the information gathering, and so it's not popular with local management and it's not too popular with senior management until they get their nose pushed out of joint by some outside force usually, and they say, "What do you mean? You don't even know who you regulate?"

RO: Well you'd think, though, Sterk, if resources were based on their OEI that it would be important for them to keep up high . . .

SL: Yes, it's important for them to discover new firms and forget those that went out of business. That's called padding, and . . .

RO: Oh.

SL: (Laughter) And we recognize that, and so we tried several times to fix it, and you can't do it long distance. So that's one of my prides and joy. I started a program to try to institutionalize the upkeep of the OEI, and we did it with a program of on-site visits where we'd actually audit the OEI using a team at headquarters and field people from the district to (Inaudible) samples. We'd take a sample of the OEI and then actually pull out the files and make sure that the data was accurate. And the way we . . . We picked some of the files by random, and we picked some of the files by looking at reports that we generated of picking out establishments that didn't look right. Like we'd have food blood banks and all sorts of strange things like that, and those of course would be (Inaudible) on-site and fixed.

RP: Those were due to data recording errors at some time.

SL: Yes.

RP: At least if you consider everybody to be honest.

SL: And so these on-site . . . We didn't call them audits, but that's what they were called. We called them reviews so they'd be more palatable. But the people that worked with us in the district made it all credible, because then when we reported to management that it was padded, they'd have to agree that, oh, it's padded. The

first go-around was like a freebie to management. We were saying, "You've got problems and this needs to be fixed." You could tell them in detail it needs to be fixed. And then we institutionalize it and it's part of the . . .

(Interruption)

SL: It's now a field management director covers it for every district. The district's OEI has to be on-site reviewed a minimum of once every three years to make sure that they've kept it up. And each follow up, each review that's done after the first round now has a written report to the ACRA about the condition, if it's in proper condition, management perceives as proper (Inaudible), and if it's not it becomes something that's used for performance reviews. And that keeps the importance of it up. That's what I'm talking about institutionalizing it.

RO: Now there are statutory obligations for the agency as far as making inspections. How do you integrate this into your planning process?

SL: Well that goes into the long-range planning and budgeting process, too. You know how long it takes to . . . We know how much resources it takes to, at a minimum, cover the industry that requires those statutory requirements. I know the ORO (Office of Regional Operations) and its predecessors have always been

cognizant of it, and in our dealings with the centers make sure that there's enough to cover those.

RO: Was that taken off the top, then, when you spread resources?

SL: The basic programs, like in drugs your GMP inspection program, is supposedly should have that at one time. Things have degenerated since probably about the last six, seven years, so we're finding that in a lot of areas we don't have enough to cover the statutory requirements anymore--devices especially, because we're running . . . We have a couple of computer programs that support keeping track of the coverage of statutory obligations, and they alert people to the fact that they're running behind and which establishments have (Inaudible), and they're supposed to take actions to correct that. But when you have a lot of emergencies in the same program area, a lot of times you fall way behind.

When I left we were falling way behind in drugs and had been way behind in devices and we were falling further behind in devices. The device inventory continues to grow steadily, and the resources to cover it have not grown steadily. They've grown in little bits. And so when I left we were probably only hitting about 60 percent of what we should have been in devices and about 80 percent in drugs. A lot of that, like in drugs, there's enough resources to do it if all of the resources were focused on it, but the program managers in the center and I guess we had to

agree in most cases that (Inaudible) a lot of the resources to other programs that needed to be addressed.

RP: Don't they also run into the situation where maybe you've got manpower to cover all of your drug plants but if you started having a violative plant that takes repeated inspections and investigations, you use the manpower that theoretically could have gone to four different plants on one because it's violative.

SL: And if they decide that they have to have a program where they do a lot of analysis of drugs to provide assurances to some constituent group that the drugs are (Inaudible), then they had to divert resources where we don't hire as many investigators and the laboratories are staffed up, and so we can do less inspections. And it's a balance. FDA's always been lean and hungry, and when we have relatively big influxes of manpower through budget increases, it's usually associated with a larger influx of responsibility. So we're always . . . And of course from my perspective, I would say all the commissioners until--short-term memories are supposed to go the other way . . . The one before the current one.

RO: Hayes?

SL: No, not Hayes.

RO: Young.

RP: Young.

SL: Young has been the first one that has been a patron of the field, and there's been a lot of other criticism of his tenure, but from our perspective, he's the one that's responsible for revitalizing the field resourcewise. The next one--I can't remember either (Laughter); I know them--has more or less followed, but it's still . . .

RO: You mean Dr. Kessler?

SL: Kessler, yes. Young is the one that turned it around.

RO: Sterk, roughly what percentage of field manpower goes to the various program areas, like broadly drugs, foods, devices, and so forth?

SL: Gee, I used to have charts on that six months ago. Gee, I would say about 40 to foods and 30 each to drugs and devices. No, that's not right; that's too much. Twenty-five each to drugs and devices, and the rest for biologics and veterinary medicine.

RO: A little bit to cosmetics and . . .

SL: Well, that's part of foods, though. That's part of foods.

RO: Oh, okay.

SL: And, of course, foods kept getting smaller and smaller as a percent of the pie. They used to be about 70 percent, and as we've added new programs . . . But for years they actually lost resources that were transferred from . . .

RP: Speaking of that kind of thing, what . . . Excuse me. How is the manpower divided roughly between the field and headquarters?

SL: Again, from my perspective, I kept a chart that I called a rape of the field for years, and we went from something like 76 percent of the agency down to about 35. I think we're creeping back up a little bit, but not much. Here again, it's moving in outside managers that are in an environment where they are bombarded by a racial something, six to eight to one, on perspectives from headquarters versus the field needs. The field manager is a voice in the wilderness, and he has day-to-day operations to manage. Although the center directors also have day-to-day operations, they have a hell of a lot more time to plead their case to the commissioner than the

field. I think the agency's planning staff was also oriented the same way and considered the kinds of operations the field did as sort of gross and vulgar compared with things that they could see in nice offices in headquarters, and so I don't think we got treated fairly there either.

RO: Sterk, when biologics and radiological health came to the agency, did they come with sufficient resources or did the agency have to absorb . . . ?

SL: Well they came with sufficient resources to do the job that they did before they came . . .

RO: To the agency.

SL: . . . to the agency. But that was more of a glad-handing job and wasn't enforcement related. In fact, for many years, biologics--again this is from my perspective, and my perspective is from what I assume from a field perspective--is that they didn't do any enforcement. So in biologics it took years to get them into the enforcement mode, and I guess again it was from the field finally proving that the blood banks were terrible and forcing them to go into that.

RP: But that in turn, then, required more manpower.

SL: Yes, yes, so then I said, "Well, they are terrible; we'll go out and inspect them once a year." So we had to divert people to do that. And a lot of diversion was in reprogramming and the budget itself. And as it got messier and messier, it got into unofficial reprogramming where each district office just said, "To hell with it. We can't do food work or drug work. We've just got to do blood banks." So until we thought we had a better handle on the blood banks, a lot of other work wasn't done. When I left it was settling down more or less to where we were inspecting them enough to satisfy the public, I guess, but probably still not enough to do a good job. I think we're down to once a year now, and in my opinion is (Inaudible). I'd just as soon have them in there once every two years, twice every year.

And some of our budget directions we were going that way. We turned our own management around because they were sort of hurting from not being able to do a lot of other program areas, so they felt that we ought to drop back to once every two years. The planning groups in ORO, I think, was able to show them that the time was right to not do that.

RO: With the change of center directors and commissioners, I guess--the commissioners more frequently than center directors--they usually come in with their own agenda. Does this call for a shift in at least their program attention and what the field does?

SL: Yes, usually the program area, the center director in the program area gets all the gravy for a year or two. That's why Young was a blessing to us, because he looked at the whole picture and became fond of the field, primarily because they could see that the people that carried out the mission on the front so to say was the field and not the centers.

I think our worst years were the Sherwin Gardner years where he was the deputy commissioner, because he had been the associate commissioner for planning and evaluation, and I don't know what his personal reasons were, if they're conscious or subconscious, but he, everything that we saw emanating from his office was like they had some vendetta against the field offices, and we could never understand that.

And Jake Barkdoll, when he took it over, I think continued it to some extent. But by the time he took over the field stature had risen far enough to counteract his negativism. Of course, in my opinion and a lot of my cohorts' opinions above and below me, Barkdoll was bad for Food and Drug as a whole because there were many years where he would be bragging that FDA got cut less than some other agencies, and this was the wrong perspective to take as far as I was concerned. The FDA has a magnificent story to tell. (Inaudible) in Congress and all the Congress are consumers too, and if you package it right, we could have done a hell of a lot better. Young did very good at that.

RO: There are a couple of other areas I wanted you to touch on. Should we take a break now and go to lunch or do you want to cover them now?

SL: Do we have a lot of more areas in the afternoon after lunch?

(Interruption)

SL: An observation that I would like to make about the history of the field was that it damn near assumed something of corporate culture against reporting data. You have a few strong-willed managers, not the majority, but they're always willing to moan and bellyache about having to spend all this time reporting and not enough time to do real work, you know. And every time you ever looked into how much time they reported, it was infinitesimal to the actual time they spent reporting. But that's sort of like a millstone around (Inaudible) get away with it.

RO: Well does that vary considerably from region to region?

SL: Oh yes.

RO: What about within a region?

SL: Yes, some districts or directors are different, too, and some of the directors of an investigations branch. But most of them want the information. See that's . . . Some of the most boisterous critics are the ones, when they get into a higher place in management, are the ones that bitch and moan the most about not having the information. They don't want to report it, but they want it.

RP: Thus it's always been. (Laughter)

SL: And it's top management that's the weakest link in the whole thing really. I think the only one from my perspective in my time that understood management's needs really, what their job was, was Hile. And he always had . . . We suffered more personally under Hile than anybody I think, because he was more willing to, rrrrrrkk, in public to us than anybody else, but at least you knew that he cared and understood that as a manager, in my textbooks anyway, it's always been that you have three basic functions of management and that's planning, evaluation, and control, and I think he understood that.

RO: Well by his very nature, he was somebody that liked to involve himself in just about every aspect of the organization.

SL: And of course Healton was the most dismal point in the history of EDRO, because he didn't give us any trouble, but he didn't do anything. We were ignored. I don't know if we were the only ones ignored or not; I suspect that might be true. But it's just that if you have skills and education and ability, you like to have management use it, because you feel like you're coming there and doing a day's work. Since top management's functions of planning and evaluation are really the basis of it, when they don't do it . . .

RP: Well he was a poor manager because of that attitude, I'm sure, because he must have operated in a vacuum kind of.

SL: And then you get somebody like Herbie Klein coming in there, and Herbie was an extremely intelligent person, but he had no controls. And he made it worse by bragging to everybody that he was Healton's close buddy and he was at his home all the time. And that just (Laughter) . . .

RO: Since Healton and Hile there has been several other managers at different levels?

SL: Yes, yes. Probably the biggest disappointment to me is Chesemore, and again I can't see . . . He was the total politician. And I knew him so well when he was in

charge of budgeting and stuff. (Telephone ringing) I've got an answering machine, so . . . And I'm not saying . . . I mean, he came in in a mess, and I guess he improved things a lot, so I give him credit for that.

RO: Well you had John Taylor in between there.

SL: That's true. Taylor was sort of like Heaton except that he . . . I think he understood a little bit more about his responsibilities in management. At the time he had already been changed to ACRA, and he had so much . . . That's a real . . . That made that into a real bitch of a job.

RP: Do you think he just had too much on his plate?

SL: Yes. Hile was the only one who could handle it because he had had both jobs before. So I'm sure that if somebody else had both jobs before and was as talented they could do it too, but . . .

RO: With the change now with the commissioner and the fact that he has a number of deputies in between there, that has changed really the ACRA's position in the agency.

SL: From number two to number eight or something.

RO: Do you see that that's going to alter that operation? I mean the ACRA operation.

SL: I'm sure it will. I just had not spent much time thinking about it, because I had one foot out the door when it happened.

RO: Ready to jump.

SL: Yes. I would have rather seen him just fill the positions he had with his own people than use this way of bringing in new people. The good news is they got rid of Barkdoll. Maybe that's worth it. (Laughter) A lot of these people, like Heaton I think is the salt of the earth. I think he's, you know, a little (Inaudible) goodness, and he wakes up and I'm sure he tries to do this wonderful every day, Food and Drug and stuff like that. And Barkdoll seems to pleasant or something like that, but the setting I just thought it was terrible, because his motives were not, from my perspective and from my knowledge of other agencies, I just don't think he had . . . That's hard to say. He either just couldn't understand, or the long-range planning he didn't believe in that. See that's another thing. We'd have arguments with him personally and everything else, and he'd finally, when you talk about long-range

planning, when everybody would lay it on him that the agency needed it, finally he said, "Well, leave it." He just wouldn't do it.

RO: Now he was the associate commissioner for planning and evaluation, and it's not clear to me at this point now how that office interfaces with the centers as far as the planning and evaluation and the impact that that would have on all of the EDRO or the ACRA field organization in their planning and evaluation.

SL: It's supposed to be the head of the agency planning and then coordinate the field and the headquarters into a total agency plan as (Inaudible) outside the agency to include the department and include (Inaudible) Congress accepting budgeting and that sort of financial management (Inaudible). As long as I've been . . . As long as the office has existed, the role they have played was like a weak referee, and they would just open the ring up between us and the centers and say, "Okay, you guys fight it out." They don't . . . They provided no leadership. All they provided was the ring and maybe clean it out afterwards. And they always had . . . I believe they always had agendas that were not favorable to the field. On the final cuts on resource planning where they were alone with the commission, I just . . . I mean, we always came out bad. Until Young (Inaudible). (Laughter)

RP: Young had the philosophy, didn't he, that he really wanted to be commissioner for a long time and run this organization. He didn't come in as a two-year man like so many of them have. And that must have had a salutary effect on his attitude, too. He was planning to live with some of his mistakes.

SL: Of course Barkdoll came in as a (Inaudible) bandit and never changed.

RO: Well he came in as Sherwin Gardner's deputy before Sherwin went to be the deputy commissioner.

RP: There's an awful lot of Washington types that tend to use the agencies as a stepping stone for themselves and not too much else, and some of us that are old timers have always felt that we were there to foster . . .

SL: Who was it that went out to be Stanford's president?

RO: Kennedy.

SL: Kennedy. Well, he got his, and I'm glad. (Laughter)

RO: While we're talking about some of these personalities, let's, you know, we could talk about some of the other immediate bosses and things, well what about some of the commissioners as you saw it from the planning?

SL: I got one taste of Kennedy, and I don't want to see him again. I saw Young in the elevator a couple of times and I just . . . At that time in my career I just wasn't even remotely interested in going to these BS meetings that he had up there, so I . . . You know where you go to the, giving some presentation to the commissioner on planning or something like that, and all the little toadies from all the offices who want to be seen race in there and sit there and, "See, Commissioner, I'm here!" And I just wasn't a part of it. I felt I was in good hands after he got his, and I know his deputy was terrible, drove Hile to distraction.

RP: (Laughter) He drove everybody to distraction didn't he? I can't even remember his name.

RO: That was before (Jim) Benson went in there.

RP: Yes.

SL: I don't know how Hile felt about Sherwin, squirming Sherwin, as we called him. I know he didn't care too much for Barkdoll. I know that. (Laughter) I didn't have enough time to think about that stuff. Our big, Tony Celeste, you know, was a terribly charming fellow and all that sort of stuff like that, but we always felt that he sold the farm with the centers on the planning system. So he had a hard time giving him a minute. He was so busy being the glad-hander and everything else, and it took us about four years to get the work plan back in shape.

Oh, the center wanted, the Center of Foods had a complaint that they didn't think they were getting enough out of their resources or something like that. In the field at the same time was the big boisterous district directors or regional directors were complaining about numbers in the work plan. "Well, if you didn't have all those damn numbers in the work plan, we could do real Food and Drug stuff," you know. And he, Celeste, he completely misunderstood the position of the center. And so (Inaudible) take the operations out of the work plan for Foods, and we'll just let them do food, good Food and Drug stuff. That's where we were for a long time, and the centers finally agreed, Foods agreed, "Okay, we'll do it for a couple of years and if we don't get more production, let's put them back in." So that was silly. We have little enough control, which in retrospect brings me back to Hile.

Remember the time when he made everybody do their own (Inaudible) analysis report, and report once a month? Something like that is not all bad. I was shocked by it having such detail at the time, but the basic point was, from the way

I understood it, was that a lot of managers didn't know what the hell they were doing. It means if you're not doing . . .

(Interruption)

SL: This goes back to the reporting. They had gone so many years without reporting and not knowing what was going on that it was a shock to them. I guess it was a result for Hile asking a couple of district directors about, "Well if you're not using the resources like they are in the work plan, what are you using them for?" And they didn't know. And of course, that again is one of your basic management responsibilities of knowing how you are using your resources, so he stuck it to them. And then as time went by, he sort of backed off and backed off. Some districts I think are still doing it, not to the detail. It's always these outside folks that have to wake management. Same thing with the OEI. The thing that got us going was the House Surveys and Investigations Committee that took a sample of 500 establishments and found that over half of them were out of business or never existed. All right. Enough of that.

RO: Before we lose it, Sterk, I noticed that you were on a roll here on the field committees. You had mentioned that at one time and then we never really delved into what their role . . .

SL: Well the field committees' role has changed, evolutionary a little bit. When they first were constituted, one of the major functions was to work in the planning process, to get like a formal sounding board to work with the centers to make sure that they had an early chance to feed in to the policy making of the center and also be a conduit for the centers to get some of their philosophies out to field management. I guess that's the best way of saying it.

RO: Well as far as the field organization, what kind of authority did they have in meeting with the centers and things?

SL: Authority?

RO: Yes.

SL: Oh, they were not . . . I mean, they couldn't speak for the EDRO. No. They were advisory to the EDRO, I'm sorry, and the ORO. Of course, advice is, to the EDRO, is a lot stronger if you totally agree with the center on what they want to do or vice versa. That's where they were real useful. The first in the long-range planning, we set up a procedure called program needs. And this was before the field committees. We'd go out well in advance of the annual planning--I can't remember this, so help me--and asked them to review all the compliance programs and other

areas of coverage to make sure that they were still addressing the problems that they were supposed to address, and tell us about ones that are a waste of money so we could recommend dropping them, or areas that aren't covered at all. Then that stuff would come back in and we'd put it in a package and send it over and discuss it with the centers.

And we kept doing that for about five or six years, and then it was decided--probably during your time again--and I don't know how it was decided to have field committees, but they were sort of worked in, and then that program needs was focused in the committees. It still was initiated by us as their monitor. And I guess they're there for those purposes and just any other communications problem that you can have one level lower than (Inaudible). It's a good idea.

RO: Well, it gave the field, who I think felt that they never had a role in this whole thing, at least it gave them an active role in meeting with the centers and telling them what some of the on-site problems really were. It wasn't filtered through the old EDRO organization.

SL: Oh, yes, I mean we were always accused of filtering stuff. From my perspective, the only stuff we'd filter out is the dumb stuff, really dumb stuff--the stuff that if it got through it would make the field look real stupid. I'm sure that maybe we screwed up on something, but . . . You know, all the stuff went back

through you or Hile anyway before it went to the center. And you all agreed that the dumb stuff shouldn't go over. (Laughter) You've got some guys that are off the wall would get the wrong (Inaudible) struck out at anything, and if they happened to be writing on that subject of what it meant (Inaudible).

RO: When the compliance programs were developed by a center for field initiation, what role did you folks have in reviewing those compliance programs?

SL: Well I always felt and the centers commented that we always did the most thorough review. We would catch a lot of laboratory problems, because we had a couple of people that were there that the science branch wouldn't pick up, and the same way with . . . We reviewed the whole program in our office. The other offices sort of kept it generically to their specialty, and we saw the whole thing. For years we would make probably about 60 percent of the comments on the compliance program that went back there. Whenever we had, we made some real technical comments, we'd always clear it with either the Science Branch, and then say why didn't you find (Inaudible)?

RO: So yours then was a review more than just to see that the resources were there for that?

SL: Oh yes. It was a program management group, because everybody that we had had program backgrounds, (Inaudible).

RO: You were primarily involved in the planning. What about the evaluation? That was another side of the house.

SL: Yes, that's another sore point. We all know what evaluation is, we think, from the textbook standpoint. But the agency doesn't like to do evaluation because it's, in our opinion, because it opens festerings. It points out festering sores that they don't want to deal with. So our evaluation branch, and I'm sure they'll be the first to admit it, doesn't do evaluations at all. What they do is they do data analysis, and then they also do monitoring of the data system itself, design of the system. But in the analysis they'll lay out stuff that upper management could use to do a partial program evaluation, but even then it's not enough, because nobody gets the information that they need. They have a long career of tries to trying to evaluate programs. The centers have tried it, too. The Foods are about the only one that really did a good job of it.

You start looking at a program and seeing what it's supposed to do, and what it did, and what it found out, is it a real good program or not, or how is the industry that you were supposed to be evaluating, and you get it into print. Then it becomes freedom of information, I guess, and then they're afraid of that. I mean, they had

to have a system where they keep it private, unofficial, or something. Then the center dropped it after two or three years. I know that Ed Steele was prouder than the dickens at having all these nice reports. They did about four or five of them. And they were great reports. It's just that they pointed out weaknesses in the agency's programs. And I think some of them got loose in the Pink Sheet or something like that and the newspaper and later (Inaudible) second-guessing and all that sort of stuff.

I don't know if (Keith) Dawson was still in charge of that or after it was (Bob) Spencer. Maybe it was Spencer. They tried to do some evaluations on field performance, different districts, and pointed out . . . Obviously, they had some districts who had real suspect management because they couldn't do most anything. And that got up to (Inaudible) level. When you see a problem and you have responsibility, you might have to do something about it. We always felt that that's what turned it off (Laughter), because they didn't want to do anything about it. And from my . . . I tried to . . . I get real upset with some regional district directors because I thought that they really were terrible managers and did some just terrible things. But I always had to sit back and say, "I'm only just seeing one aspect, and you guys up there are seeing how they perform and everything. And they must just be wonderful in some other ways." I didn't get a sour stomach or nothing, you know.

RP: You know, talking about the field managers, really up until the late sixties, field managers at all levels didn't have any formal management training of any kind. I think until Goddard came in it was not unknown but very rare. Over the past number of years since that time, our field managers and growing up, the younger people going up who eventually become managers all have had considerable training. Can you make any comment about the difference between the managers who were there when you came in, none of whom had had any management training?

SL: Yes, I think the best thing is that the ones that do get the training don't use it right. I think the managers before are every bit as good or maybe in some cases better, because I haven't seen any improvement. I mean, they all get this sensitivity training to people, and they end up going overboard, I think, in the wrong areas and spending too much time and letting people get away with stuff so it doesn't bother their little psyches.

RP: The earlier managers were sort of intuitive managers, and . . .

SL: And they weren't encumbered by all this political correctness and all this other stuff that just blows my mind. I always sought out diversity in the people I hired, so I had the first woman up in headquarters, (Inaudible) the one that worked up to the laboratory. I had to fight Dawson tooth and nail to hire Miss (Inaudible), Lois

Beaver. "If she's not married and she's working, she must be a tramp. She'd be just a divisive force, you know." Anyway, and I've hired a lot of women and blacks and Hispanics and everything else. I've had a lot of complaints about being prejudiced, but they didn't last too long.

RO: Bob, to go back there to the sixties and things that you were talking about when we didn't have any really formal management . . . I remember when (Winton) Rankin was the deputy commissioner--that would be right before Goddard--that he insisted that all the district directors were going to go to the AMA training course. That was one of the first things. But before that, why, it was a number crunching thing. I can remember being in the field when we'd get a notice from the old planning and evaluation section there: we were supposed to have done fifty PEPs (public eating places) or something and you've only done thirty; what's wrong? Well, by golly, before the month was out, we made all fifty of them. And they weren't concerned what . . .

RP: But that's a poor example, because we had a special appropriation back in those days . . .

RO: I know, to do that.

RP: . . . and you really . . . Yes, use another example, because that one's a poor one.

SL: If you make a commitment to Congress that you're going to cover half your big establishments and a district doesn't cover half of them, you have a responsibility for speaking for the agency. And if there's a good reason why not, you call them up and say, "Why didn't you do it?"

RO: Well, but right now where there are statutory obligations, and you don't make them, and you're willing to go back to tell Congress why you haven't made it.

SL: Yes.

RO: And those other PEPs . . . It's a poor example, of course, but . . .

SL: It's different now. We have enough . . . We've also got enough information to be able to tell them why we didn't do it. And they're pretty sensitized out there now to at least tell us why they didn't do it, you know. So in the old time, they'd just say, "Don't bother me. I'm doing good Food and Drug stuff."

RP: PEPs is a real bad example, because you could send one guy out for a day and pretty near make your quota if he . . .

RO: Well, that's what happened.

RP: Yes, I know.

RO: And that seemed to be the only thing they were interested in. Well, anyway.

RP: I think it was. (Laughter)

RO: Well, that's right. But what you accomplished by it is another thing. And the other thing was the number crunching as far as your actions were concerned--you were a little more interested in being sure you've got seizures and things and anything else.

SL: That's where I think the shortfall of this later-day management is that they don't teach management of a company so much as they get preoccupied with this personal development and personal interaction. That's just, I think it's proving to be BS. It's hit its high twenty years, and it's, people are going back to more basic things of what in the hell do you get up everyday for, and let's do it right, and let's do it

effectively, efficiently. And that's getting back into focus now. That's, of course, my opinion. I could find a lot of backups for it in modern literature, but it's . . .

RP: Well I asked you the question about the old managers versus the new ones because if I think back in my career, which now has gone fifty years (Laughter), when I try to think of the best managers I've known, they were in the earlier rather than the later period in my experience. And as I say, the early ones didn't have . . .

SL: We used to have investigators I know that were braver than hell until (Ken) Lennington came out or something like that and they'd shake in their boots. But there was a hell of a lot of respect for power and sort of like that.

RO: Oh yes.

SL: And that wasn't all bad. A lot of it was overdone, but you knew these guys knew Food and Drug, and you could forgive them for a lot of excesses in management with (Inaudible) at the time.

RP: Well we had people like Rayfield who was extremely able in the sense of getting the field to do good work and produce properly, but who somehow in his

interpersonal relationships kind of spoiled it all. (Laughter) At least, you know . .

SL: The funniest thing was that I came up here on a two-week training thing, spent an afternoon with him, after hearing what a terrible SOB he was, and watch one eye because if it starts doing this, got a lazy eye or something, and he was as nice as pie to us. Just . . . (Inaudible) the ogre that we've heard.

RP: Well I had that experience too. Dealing with him from afar was bad, but when I came to Washington and suddenly because of reorganization found I was working for him and had to deal directly with him, my problems with him pretty much vanished. He was a strange man. But you're right that that kind of firm direction had a lot to be said for it.

RO: Yet I think that was the end of it. When you consider, you mentioned Lennington and Fred Garfield as far as the chief chemists were concerned, but when that crew left, why there wasn't the awe of a headquarters group that . . .

SL: Well I think Hile had a lot of it, but he had a lot of . . . Here again from the little I picked up, he had a lot of . . . Since he didn't have a long field period, a lot

of the field managers gave him short (Inaudible) back first, but he worked over that pretty well. Chesemore had a lot shorter field thing and worked over it.

RP: Well Paul worked up in the field to be a supervisor in the field.

SL: Yes, Chesemore worked less than two years before he went into the executive program, one of those middle level . . .

RP: Chesemore was . . . I remember when he was in Budget Branch. He was really a sharp young man who did good work in the Budget Branch. I always thought very highly of him.

SL: Yes, and I always worked with him and I was really disappointed when he became a political animal. He used to pick up the phone and call me direct from there all the time, and I'd be able to give him the information on budget stuff like about in thirteen seconds or something like that. Always had it at my fingertips. And I don't know if Gerry Meyer, another person that didn't like the field too much, rubbed off on him or not.

RO: Well there were certain field people that Gerry liked very well and others that he didn't care much about. But . . .

SL: That's another one that I sort of liked him, admired when he first came, but then I could see that he was a total politician too.

RP: Which when you get to be at a certain point, politics inevitably plays a big part in what you do.

SL: But the EDRO was total politics. I mean, you can be a politician and keep your basic skills and direction, and then your politicking can help.

RP: Yes, that's true.

SL: But when it replaces totally and . . . It's like (Inaudible) said about (Ross) Perot and General Motors when he got in there and started stirring things up, and he said, "All high level executives are spending about three-fourths of their time working on their next promotion and not managing the damn agency," and that got them upset and they bought him out quick. But it was true.

RO: Well before we get too far adrift from some of this, we talked a lot about planning as far as the domestic programs that the FDA has responsibility for. And one of them we didn't talk much about is imports.

SL: Yes, and imports is basically a food problem. And both our domestic and our imported foods are, we have terrible coverage on. If you want any assurance of both good foods and economic honesty and stuff like that, it's just an overwhelming problem that we don't have anywhere near the resources. We go through and develop data on the coverage of the food industry and--(Inaudible) the imports--but we were covering the average food establishment about once every seven years. And knowing when the average small food company goes in and out of business in about three years, half of the industry we never covered, never will cover.

And I did get that in the budget. I take personal credit for that, that I've got it in the budget now. I mean, it was in at least for two years before I left that our aim was to cover every food establishment once every two years at least. And I firmly believe that we ought to have a goal like that. When look at it, you have, like a sixteen-hour inspection once every two years represents less than one-half of one-tenth of a percent of the time that they're in production. And USDA have people in the meat plants 100 percent of the time. Something's wrong.

Imported foods, of course, is a nebulous thing, because we really don't have enough information to know what's coming into the country, where, when, and how much in advance as (Inaudible). It's all reactive. And you have some patterns that more food will come into one port versus another port. It's the kind of thing that importers if they get into trouble in one port can go port shopping. Our level of coverage was arbitrary. We were trying to pick it up in planning to make some kind

of a goal that we could use in planning documents for management to adhere to as their own philosophy. I think we guessed that we were covering about, in the olden times, I think they said something like 20 percent. Dawson and Lechus did a lot of work on this. You could check with them. And then over the years we could remember . . . I think there was used in something when (Dick) Kluge first started working on that . . .

RO: Import strategy.

SL: Yes. And over the years after that it drifted down so that we estimated we were down about 5 percent or something like, and we put it in the budget document that said we wanted to increase it back up to 8 percent or something. We got a couple of influxes of resources. And then I think Congress keeps asking us for . . . I think we're still using 20 percent as the ideal goal or something like that--one out of five entries. And they said, "Well, why do you set a goal?" We really don't know. It just seems reasonable. So a lot has been written about that.

Imports always was a place that it was easy to siphon off resources, and we got concerned back about the time that the import strategy was on to at least freeze it where it was. And we put into our call documents to the centers that this is what we're using; don't cut it, because we've committed ourselves as an agency policy to Congress to keep this level up. And even as late as a couple years ago we had a

couple (Inaudible) with the centers that cut it. In most cases it was just they forgot. It's the most nebulous job as planners we've ever had, because it's so hard to define what coverage you should have; it's hard to define what's the what of what you're covering; and it's, for the field people, it's not quite as glamorous work, so you always have that part working against it, except the ones that have separate organizations. They seem to be able to do a pretty good job keeping up . . .

RP: Is that New York?

SL: Yes, and L.A. L.A. probably has the best one. But it's a problem that's so big it's sort of mind-boggling. You don't . . . It's hard to get a hold of, and it's hard to get anybody to agree what should be a target and then how to measure it.

RO: Well I think a lot of the domestic manufacturers complain because they feel that the imports are getting a free ride on a lot of these things and there's undue attention given to the domestic manufacturers. So somebody in Congress decides that the agency should give more attention to imports.

SL: In some areas of the country they're saying just the opposite--they're not covering domestic--and they're right.

RO: Yes.

SL: Oh well. Those are fun kind of problems. My job was always fun. There were some times where I was having problems at home where nothing was fun but--I mean with hyperactive kids--but that was a big career mistake, too, having too much fun. I should have got the hell out of there. (Laughter) But I didn't have any mentor to guide me, you see.

RP: Your mentor left.

SL: He retired, yes. (Laughter)

RP: He wasn't much help to you anyway, was he? (Laughter)

SL: Oh yes. Anyway, and then Dawson used to burn me up when he . . . He would tell, I don't know whether you or Hile or Heaton or something, that I was madder than hell about something, and I wasn't madder than hell about anything. Let me tell people if I'm madder than hell; don't you tell them. Was I really very (Inaudible)? Since then I've been told that some of my facial expressions indicate that I'm irritated (Laughter), but I never . . .

RP: Well you had a right to feel strongly about some of your opinions.

SL: Yes, but I was always a company person.

RP: Oh yes.

RO: I guess one other program area we haven't touched on at all, Sterk, and that's whatever they call them now is consumer specialists or media or what, and how did we plan . . .

SL: More than one . . .

(Interruption)

SL: The people that we lovingly called the "cows," the CAO's--that's an Italian pronunciation--were really a godsend, because I don't know, I had to do it two or three times myself out in Chicago, go out and give these little public talks to the church groups and stuff like that, and I didn't like that at the time, although I could probably do it now with much more ease. And those take a lot of time, because we had a lot of notoriety at the time, and we had a lot of requests. And then they hired these first women, and they did a good job. A lot of them were, most of them were

highly professional. Quite a few of them were rough around the edges because they had to fight their way, claw their way up in the man's world. But you can forgive that, I guess. I mean, I can understand. But I think they did a super job. At least the ones I knew in Chicago, they got out and made contacts, and they developed more and they quickly learned the gospel as our corporate culture had it and did a good job, I thought.

RO: Planning for their time.

SL: Oh yes. That's another nebulous thing, but we sort of traded them . . . They wanted to be in the work plan, so we . . . We get less complaints about people being put in the work plan than we get from those taken out, because the ones . . . The consumer affairs we put in there, and we tried to structure what we thought would give them some guidance from the centers to how much time they should spend on different subject areas without a lot of real finite data. And the centers worked it into the call to the centers so that they could spend some time in reviewing where they thought the needs for public information were, and they could write it in their little compliance-program-like forecast that went into the work plan. I thought it was sort of superficial from my perspective, but we got a lot of feedback from consumer affairs officers that they really looked at it and cared about it and followed it. So we

took it out I think about three years before I quit and got a lot of complaints and put it right back in.

RO: You mean as far as reporting was concerned?

SL: No, the work plan, took it out of the work plan.

RO: Well they had to report certain activities.

SL: Oh yes. And they had their own quarterly reports that they used the work plan as a general guide. So it . . .

RO: Was there any qualitative evaluation of their activities?

SL: Not by us. No, it was Claudette's (Guilford) office was supposed to review the quarterly reports and, no, I don't really know what was in those reports.

RO: From a quantitative standpoint, but I was wondering qualitative.

SL: Yes, she had to do it. I mean, see I don't know if enough was in those reports to make a quality evaluation. There should have been. When you talk about the

data systems and people being in plans, when Hile had his second coming, he was considerably changed and erroneously more sensitive to field management, I believe. And again, the most boisterous and somebody ill served of them got him reporting again. So he made Dawson review everything that we put into the system and come up with a recommendation to eliminate some of the reporting.

RO: Yes.

SL: And Keith blew it. They had about . . . His old good soldier without thinking had about, he and Lechus, had about three levels that we could cut back, 80 percent of it.

RO: We did.

SL: Wrong.

RO: Well we cut back.

SL: Yes, but he presented it wrong. He should have gone the very first level with just a little bit off, and then, well, if you have to add more we can take this off . . . He gave the whole thing and pppppth. All of the . . . Well, the compliance officers

didn't bitch much, but all of your special program people, they were just crushed that they weren't important enough to be considered, tell what we were doing. And that hurt us, too, because I mean it just took away a whole bunch of information that we had to use to give the very same wonderful leaders information that they had to have. "We don't have that anymore." "Well, why don't you?" "Because you took it out." "Oh."

You've got the CAO's done?

RO: Yes.

SL: Let's see. Oh, another thing--I mean it was sort of a quirk--our whole planning system is probably best called like a manpower management system. It's like an accounting system for planning the use of manpower through the use of program operations and stuff like that. Well the department came down saying, "With this new management theories we've got and everything, we have to have a strong manpower management system. And you will do this, this, and this. And we'll have people coming down here to make sure, to see how you're doing, and we're going to rate you and all that sort of stuff." So they made their first arrangements to come down and see what we were doing in FDA, and it got screwed up somehow to who in the hell they should talk to. And they sent them to restful Roy Keeny. "Well, they've got personnel." And he didn't . . . Poor restful . . .

RO: Roy.

SL: Poor Roy was out of his element. He's probably a couple of levels above his level of effectiveness or whatever you want to call them, and he didn't know what the hell was going on. He didn't know what anybody else was doing. So the department people left and said, "Well, FDA's field, they don't know what the hell is going on. They don't have any program or anything else." And I'm sitting here, and here we've got the state-of-the-art, the closest, by far the best system in the federal government practically--and I would bet on not even practically--and I said, "What the hell's going on?" So I turned into a Tasmanian devil, frothed at the mouth for a while, and I got things reoriented, and the guy came down to us and he went back with glowing reports about FDA. For one year we had big trouble on the budget because the department said, "FDA doesn't know what the hell they're doing." That's that little incident.

Let's see. Computerization, that's another thing I was thinking about. When I was out in Chicago after about three years we started, we had the (Inaudible), and then they started computerizing the T & Ps, I guess it was. No, no, it was (Inaudible) system.

RP: With Mark . . . Yes, it was one of the new data systems.

SL: And they got these accounting machines. I went over to a couple of courses at the IBM headquarters and training session, and they were doing things then, twenty-five, thirty years ago, that we're just picking up like five years ago here, and it just blows my mind that we could be . . . We're like kicking and screaming into the twentieth century, and back then they could do so many things. And we've got guys now that . . . You have high-powered, intelligent drug detail men and other kinds of salespeople and management consultants that are on the road with these little notebooks that are hooked up to the central computers and stuff like that. And it can be, you know, like your UPS drivers, that's pretty limited what they're putting in, but you've got other technicians for major chemical companies, and they are doing every bit as difficult reporting as our people are doing, and they've been doing this for a long time, about ten years. And here we're . . . I mean some of the communications (Inaudible) now we talked about fifteen years ago and ten years ago and five years ago. We should have been on line, I would say, about fifteen years ago. An investigator ought to have been able to report everything he did at least to a T & P level, probably a hell of a lot better and in less time. It always blew my mind. It was just one too many crosses for me to bear.

RO: Well we talked about, do you remember a guy by the name of (Bob) Angelotti in Foods? He always talked about, especially on imports, if that's what the import inspector would have had, he'd be out on the dock and he could just access. And we

looked at Angelotti--of course, you had to know him--why you'd look at him kind of askance, but then you'd look at him . . .

RP: Well we had what you might call prejudices, but you have to remember these people--we all did; it was kind of the way we grew up--but we had people like Rayfield, for instance, who would not put up with anything but a completely narrative report. We worked on him for years to get just checklists, and it was never accomplished until he was gone even though . . . I think that's right, isn't it?

RO: No, we had some when Rayfield was still in.

RP: Well that was that study, whatever we called it--I've forgotten.

RO: Mary Dolan was working . . .

RP: Yes. But anyway . . .

SL: Are we on a new tape yet or is it still going? There are a couple of other things that I wanted to mention. I think this was after you left, but one of my ideas that I take credit for is our planning and evaluation trips we used to take out to the field, and I thought they were very successful. In '80 I think we cut them out because

of funding one year and never got them started again. But at their height, I would count . . . We'd figure out the districts we were going to cover that trip, and we talked to the districts, and we asked them what particular areas they were interested in talking about besides general planning and evaluation. Then we'd contact those centers, and we'd get a representative of the center to come with us. And I remember renting vans when we'd go out, we had so many people. (Laughter) But those turned out, I thought, really good. I mean the people . . . I mean the center was pretty nice afterwards. They had a chance to ask the center representatives some pointed questions, and the center people had a chance to ask the districts some pointed questions. I think it may have been the field committees took over a lot of that stuff.

RO: Did you ever have anyone from any of the other centers besides Foods go out on those?

SL: Oh yes. We always had somebody from Foods, Veterinary Medicine, and Drugs, and then the last couple we had . . . That was in case the districts asked for them, and sometimes we'd bring them anyway. But we usually had three or four centers represented every time. We had one trip where (Dick) Terselic went. That was an infamous trip.

RP: (Laughter)

SL: That should be in the record. Off the (Inaudible) personal time was just, it blew your mind. (Laughter) He was another favorite of Hile's.

RO: And mine.

RP: And mine.

SL: And Foods always sent somebody that was a very good representative, either Steele or (Mike) Olson or (Doug) Tolen. They always did a good job. I remember one visit we took Ed Steele was with us down at Atlanta. And George White was the district director down there. And that was one of my most embarrassing times, because we were in there at the office and George White really laid into Ed Steele about they were never doing any evaluations, and that was the year that Ed Steele had done those first beautiful evaluations, had them published, and they were right on the desk in front of George White. "They're right there! What do you mean you don't . . . " (Laughter)

RO: I thought maybe that was some of the earlier ones that . . . I remember Foods did some early ones and they said it was an internal document.

SL: Oh well. But it worked out pretty good, I thought, and everybody was happy. But if you're working on a lot of them it got pretty tiring, because you were moving. We were trying to cover a day per district and a half day for regional office. And then you did about three of them; that means you had a different bed for four nights in a row.

RO: You probably didn't get enough time to spend in each one.

SL: Yes, and then, of course, in '8- . . . I don't know. I don't have enough records here, and my mind's slipping. But we started these OEI visits. We sort of made those into a planning visit also at the same time. And we'd get working with these people on the OEI, and they're always usually supervisors and sometimes DIBs who'd work, and you'd spend all day with them and you get a chance to talk quite a bit about weaknesses that they perceived and questions that we had and stuff like that. It worked pretty good. I don't know if . . . Hopefully they'll keep the OEI stuff--they should--because the evaluation side hardly ever got out. John Lechus was with me once, and that was an abbreviated visit to Boston that he had already been up there for something else. And Dawson never got out.

RO: Well maybe they'll have to bring you back as a consultant.

SL: To know your enemy is to love them, just remember. (Laughter) And if you . . . (Inaudible). (Laughter) You can talk about those son of a bitches up in headquarters every day and they get you upset as hell, and then if he comes out and spends a couple days with you and you see that he's really an all right guy and cares about things that you do, and all of a sudden he's not a son of a bitch anymore. But it he's nameless and faceless . . . Or nameless. I mean faceless.

RO: Faceless.

SL: Yes, something like that. Well, some of them think they're nameless, too.

Let's see. Oh, the reorganization study. That's another little anecdote that I thought was . . .

RO: Which reorganization study?

SL: This is the regional reorganization. There's two of them. The other one was a laboratory consolidation study which was not as nice. I mean the study itself was every bit as nice, but we spent a lot of time . . . A lot of the stuff in my mind, the way I planned it was going back to the days you know you did that study where that Professor Whatsamajigger that made those beautiful maps with the lines and the holes and stuff like that.

RP: Oh yes. Hmm.

SL: Anyway, I always thought that was a piece of art. Somebody stole my full-sized one. The idea was to try to quantitate all the work loads that we had as best as we could, and then the OEI was fairly easy to quantitate, and then we weighted it programmatic-wise, and we had sections that we worked on for pesticide work, and we were really detailed then, to get workloads. And then we went through probably about 150 different permutations of organization with regional offices and lots of district offices and most of them were (Inaudible), but . . . I also did a later study I get mixed up with this. And then what the staffing would be if you related them like that, and I think . . . And then showing what the workloads for each district would be under each different variable. And we got it down to I think a recommendation of four different things. We highly recommended the four regions, each with six districts, I think.

RO: About of equal size?

SL: Yes, all these things were equal size. And I think our arguments were compelling, expanding control for the ACRA and everything else. Well, of the ten regional regions, four were vacant. So the mind set and the anguish over the

decision making took about three seconds I think. They said, "Well, we've got six regional directors. Let's pick the option that says six regions."

RP: I was on that committee, and I agreed . . . Of course, it was natural for me, I suppose, to agree with you, because you were doing the same kinds of things I used to do, but I did think it made a bit of sense. And I voted that way if we had a formal vote. I don't think we did. We had a . . . We talked about it, and then Hile decided what it was going to be. But there again, politics can affect . . . (Laughter)

SL: "What am I going to do with two regional directors that have no region?"

RP: Well, plus the fact that you know you're going to have to fight some Congressman for every office you close, which was probably a more compelling rationale, if you want to call that a rationale.

SL: Yet the presence was not closing the city in any case, because you always had a district office left.

RO: But it was the status of having a regional office.

SL: And here again, when we first started working on this, we found out that here we had been belly-aching about being forced to go into a ten-region, and we never had to go into this if somebody had done their job and found out what was going on, because a number of agencies never went into it, and we had compelling reason not to go into it, and we didn't have to. But we did. I mean, it was outside of our purview . . .

RP: Well we were instructed by the department to go into it. Now you mean that we didn't argue at the department level?

SL: Yes.

RP: I guess that's an easy . . .

SL: In fact, the department didn't go into it.

RP: But that's fairly easy hindsight sort of thing, too.

SL: And we went back and looked at the original directors from the administration, and they gave all sorts of loopholes why you didn't have to go into it, and all you had to do was make your case.

RO: I thought at that time that Charlie Edwards was pretty much on the agency side of not having to conform necessarily with HEW because we were different enough.

SL: Somebody just didn't do it (Inaudible). The other study we did in retrospect--I keep wanting to say in rectospect, but in retrospect, because that was the funny catchword that everybody wanted to use for everything--the laboratory consolidation study, we felt that we had to do something of that sort because we had so many laboratories that were like only a third full of people. And all of that extra equipment--you know you try to keep all those laboratories equipped--it would be a lot more efficient and a lot more effective, because you could spend the same equipment money in fewer places and get better equipment, that we ought to consider closing some laboratories, Buffalo and Minneapolis and stuff like that. I say in retrospect because as it turned out we got big increases after that was pooh-poohed and we needed the space, but at the time we had good cause to close I think four laboratories and recommended so, and the commissioner bought it, and then the politics started and it stopped. So sometimes in the end politics did well.

RO: Well within a region, though, didn't they consolidate some of the work?

SL: Yes, and so that was the other . . . The tack then was to at least increase the effectiveness and the economies of laboratories by specialization. And they did that. I think the national specialization was one that we always had, and that was a few more rows came on line, but within the region ones, a lot of that was just window dressing and not too well thought out. Some of it was pretty good. The microbiologists, of course, they did that early with them because they never got big enough in a lot of districts to have more than one or two. So anyway, we . . . That was one that worked out all right.

The Heulton/Klein era, that was the worst time. Not only . . . We could do any damn thing we wanted; it's just that you want to be able to do something for somebody that is aware what you're doing and really appreciates and involves himself, and you're doing something they want you to do. We just did whatever we wanted to, and that's terrible. You can have a lot of fun doing that sometimes, but we need to sit down and think and say, "Well, what's the meaning of life?" and all this sort of stuff. And Herbie--and I like Herbie--it's just that I just didn't like where he was, but he just irritated so many people, and then they would start throwing stuff. And when you're next to somebody like that, you get splattered all the time. And I got splattered all the time, and I'll tell you, by the time Chesemore came in there, I had really got sort of bitter toward a lot of the field managers, because they're just constantly taking cheap shots at our shop, you know, just because we're next to Herbie. But I turned around pretty quick after that.

RO: You recovered.

SL: Yes. It's just like having a sore and somebody goes echhh, rrrrr. (Laughter)
So that's about it. I had my say. Anything else we need to discuss?

RO: I don't know. Bob?

RP: I don't . . . I'm sure I'll think of something later, but I don't now.

SL: Food and Drug, as I explain to a lot of people that have never had any experience in the field, when I try to orient them onto the culture of the organization, is that most Food and Drug people come to work knowing that they have a purpose and you can understand it, you know. I have a real meaningful agency goal. And when you're out there as an investigator or as a chemist or a lab type or a compliance, I mean, you come to work, and you see what you do, and you know it's good, and you can see the results of it, and everybody recognizes that it's good except industry sometimes. And I feel sorry for these people, like you work for GSA or something, you go to work and make out a manual or telling somebody that they're not following the manual or something like that, and that's terrible. But these kinds of things I think are infective. I had to go out in the field with all these guys to listen to all that BS (Inaudible). And if you can talk . . . A lot of people, when you get

out to the field and you don't really know what the hell they're doing, you're going to have a hard time communicating. I was out enough so that at least I could wing it. (Laughter)

RP: Well what you say is very important I think, which is a tremendous change over the years in the administration, because, except for a few high-powered scientific types, the whole agency was really staffed, headquarters was staffed with people who had come up from the field, except for there were certain scientific laboratories which that's not true. But from the administrative standpoint, commissioners that would come all the way up through the field and most of their assistants had. And in addition, the scientific people went out to the field a great deal.

SL: Yes, yes.

RP: You know, we had people in Division of . . . What am I trying to say? The Bill . . . Who were we talking about at lunch?

RO: Eisenberg.

RP: The Bill Eisenberg types who spent a very material part of their time in the field.

RO: Work ethics.

SL: Work ethics, I guess, and productivity and stuff like that. You know, when I came into the Food and Drug Administration everybody--the laboratory not so much, because we know about laboratories--everybody else was not 9:00 to 5:00. I know the laboratory on occasion responding to the greater need to work overtime.

RO: 10:00 to 2:00 (Laughter).

SL: Anyway, and you see it in the data of course . . .

(Interruption)

SL: But when I came in it was usual that the average T & P (Inaudible) would have like four or five hours of overtime on everybody in the investigations branch and some laboratory people. But, we also, you never had less than a two-week road trip, which means that you got a lot more overtime because you'd be writing reports on weekends . . .

RP: You mean that more overtime was put in; you weren't paid for it.

SL: Oh yes. It was unpaid overtime, and a lot of our historical data that we've used has had to be revised considerably because that particular professional ethic no longer exists where you stay until a job is done no matter what time it is, or always give a little big extra for the gipper, you know, and stuff like that. So production is relatively way down per person. It used to be that the average inspector would do a hundred and . . .

RO: At least a hundred.

SL: . . . EI's a year or he wasn't one of the salt, and now you're lucky if a prolific one gets thirty.

RO: Well, of course, there's a different type of inspection, too, I think now.

SL: Yes, (Inaudible). But on the ones you can sort of compare are way below.

RP: But when I first started doing, came to Washington, was a T & P, it was about 100 inspections and 300 sample collections a year.

SL: Yes.

RP: But you aren't measuring the same thing; there's no question about that.

SL: But you can look at the time here, how they're spending their time and say, "Well, he used to spend 50 percent of his time on, of his reported time, on inspections." Now it's something nebulous like investigations or not even that. Well what do you do? And the, when I go out and talk with the supervisors, they don't know either, because they don't have any data system to tell what the hell they're doing.

RO: Sterk, you mentioned investigations. Now the agency is getting a new breed of (Inaudible) on board, criminal investigators, and are they going to be part of the work plan?

SL: When I left, no. It's going to be a separate group all planned out of headquarters, and that's the way it was when I left. That's been a long time ago now.

RO: It hasn't even been six months.

SL: Yes, but totally unassociated with the field offices out there. They don't want any crossbreeding, although if they don't have enough manpower on a certain case then they can bring in the district offices, but they're supposed to be . . .

RO: An entity unto themselves.

SL: Yes.

RP: Supervised out of headquarters?

SL: Yes. And not co-located any place. That was the philosophy when I left. Whether or not we would pick up assisting and planning or not, I don't know if that would happen or not. That might logically follow, but it would be separate from the field planning.

RP: I have been told that there is a major change going to be made in the data system this year. I'm sure that planning must have started long before you left. What do you know about that?

SL: I don't know what you're talking about. (Laughter)

RP: Oh, okay. Is this something Lechus' group would have been doing rather than yours?

SL: Yes, it probably would. We discuss it, you know, BS (Inaudible).

RP: Oh, okay. Well I just thought maybe you had taken part at least in some of the initial work on it.

SL: Maybe it's to get some of the stuff back in that was taken out the last time.

RO: Well, should we end this session?

RP: Do you have any kind of . . .

SL: (Inaudible) be said.

RP: You've had your say.

RO: Well, Sterk, we'll get this transcribed, and you'll have an opportunity to review it, edit it . . .

SL: Did I say that? Yes, I don't know. A lot of this personal stuff, (Inaudible) observations and sort of (Inaudible). There were some tough years there.

RO: But they were fun years. Gee, do you want to go out and help him find his ball? I think he really shanked that one.

SL: Yes, I heard it (Inaudible).

RO: Well, thanks a lot, Sterk. We'll close this off.

SL: Well, I appreciate that you considered me.

(Interruption)